



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-21-0210; Docket No. CDC-2021-0102]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a continuing information collection project titled List of Ingredients Added to Tobacco in the Manufacture of Cigarette Products. The proposed collection allows CDC's Office of Smoking and Health (OSH) to collect information about the ingredients used in cigarette products, a responsibility that has been delegated to CDC by HHS.

DATES: CDC must receive written comments on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2021-0102 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-H21-8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS H21-8, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each

proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

List of Ingredients Added to Tobacco in the Manufacture of Cigarette Products (OMB Control No. 0920-0210, Exp. 4/30/2022) - Extension - National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Cigarette smoking is the leading preventable cause of premature death and disability in our nation. Each year more than 480,000 deaths occur as the result of cigarette smoking-related diseases. The CDC's Office on Smoking and Health (OSH) is the lead federal agency for comprehensive tobacco prevention and control. Since 1986, as required by the Comprehensive Smoking Education Act (CSEA) of 1984, which amended the Federal Cigarette Labeling and Advertising Act (FCLAA), 15 U.S.C. 1335a, CDC has collected information about the ingredients used in cigarette products. HHS has delegated responsibility for implementing the required information collection to CDC's OSH. Respondents are commercial cigarette manufacturers, packagers, or importers (or their representatives), who are required by FCLAA to submit ingredient reports to HHS on an annual basis.

Respondents are not required to submit specific forms; however, they are required to submit a list of all ingredients used in their products. CDC requires the ingredient report to be submitted by chemical name and Chemical Abstract Service (CAS) Registration Number, consistent with accepted reporting

practices for other companies currently required to report ingredients added to other consumer products. The information collected is subject to strict confidentiality provisions.

Ingredient reports are due annually on March 31. Information is submitted to CDC by mailing or faxing a written report on the respondent's letterhead. All faxed lists should be followed up with a mailed original. Electronic mail submissions are not accepted. Mail Annual Ingredient Submissions to Attention: FCLAA Program Manager, Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway, NE, MS S107-7, Atlanta, GA 30341-3717.

Upon receipt and verification of the annual ingredient report, CDC issues a Certificate of Compliance to the respondent. As deemed appropriate by the Secretary of HHS, HHS is authorized to use the information to report to Congress the health effects of ingredients, research activities related to the health effects of ingredients, and other information that the Secretary determines to be of public interest.

There are no costs to respondents other than their time. The total estimated annualized burden hours are 358. OMB approval is requested for three years.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per	Average Burden per Response	Total Burden (in
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			Respondent	(in hours)	hours)
Business Entities	N/A	55	1	6.5	358
Total					358

Jeffrey M. Zirger,

Lead,

Information Collection Review Office,

Office of Scientific Integrity,

Office of Science,

Centers for Disease Control and Prevention.

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